UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

PHARMACY, INC. PRODUCTS LIABILITY LITIGATION)))
THIS DOCUMENT RELATES TO:) MDL No. 2419) Dkt. No 1:13-md-2419 (RWZ)
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MEMORANDUM OF LAW IN SUPPORT OF MOTION OF THE DEFENDANTS, ABDUL R. BARAKAT, M.D., AND OCEAN STATE PAIN MANAGEMENT, P.C., FOR COURT ORDER COMPELLING THE UNITED STATES GOVERNMENT TO DISCLOSE RELEVANT PORTIONS OF GRAND JURY MINUTES

Now come the defendants, Abdul R. Barakat, M.D., and Ocean State Pain Management, P.C., in United States District Court, District of Massachusetts, Civil Action No. 1:13-cv-10943-RWZ, and respectfully request that this Honorable Court issue an order compelling the United States Government to disclose certain relevant portions of grand jury transcripts from the criminal matter <u>United States</u> v. <u>Cadden et al.</u>, 14-CR-10363, pursuant to Federal Rule of Criminal Procedure 6(e)(3)(E)(i). The defendants seek only those portions of the transcripts which include testimony relevant to the issues of (1) New England Compounding Center's ("NECC") compliance with federal and state regulations regarding compounding pharmacies, (2) the sanitary conditions at NECC's Framingham facility, and (3) information provided by NECC to customer clinics regarding such compliance with applicable federal and state pharmacy regulations. Grounds in support of the request are as follows.

FACTUAL BACKGROUND

The above-listed case is one of alleged malpractice in which the plaintiffs, Craig and Joan Simas, allege that the respective defendants provided negligent medical care and treatment to Mr. Simas between May 2012 and October 2012, resulting in injuries. The plaintiffs allege that the defendants, Abdul R. Barakat, M.D., and Ocean State Pain Management, administered contaminated compounded methylprednisolone acetate in the form of epidural steroid injections, and that this alleged negligence caused Mr. Simas to develop fungal meningitis. The plaintiffs filed a Complaint and Jury Demand in Middlesex Superior Court on November 23, 2012, Civil Action No. 12-4591. The case was transferred to the NECC Multi-District Litigation ("MDL"), Docket No. 1:13-md-02419-RWZ, on April 16, 2013.

As of November 3, 2013, the Center for Disease Control (CDC) reported 751 cases of fungal meningitis, stroke due to presumed fungal meningitis, or other central nervous system-related infection meeting the outbreak case definition, in addition to paraspinal/spinal joint infections and peripheral joint infections. The CDC reported cases in Florida, Georgia, Idaho, Illinois, Indiana, Maryland, Michigan, Minnesota, New Hampshire, New Jersey, New York, North Carolina, Ohio, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas, and Virginia, all linked to methylprednisolone acetate compounded at NECC. Of the 751 reported cases of fungal meningitis, at least 64 people have died (in nine different states). The CDC estimates that at least 14,000 patients were administered injections from three recalled lots of methylprednisolone acetate from NECC.

On February 12, 2013, the Judicial Panel on Multi-District Litigation issued an order under 28 USC § 1407 transferring various proceedings throughout the country to the United States District Court for the District of Massachusetts for coordinated pre-trial proceedings. The

MDL case is currently before the Honorable Rya W. Zobel. Discovery in the MDL and the criminal case brought against NECC higher-ups are both proceeding before the Honorable Jennifer C. Boal. At this time, formal discovery on issues common to all plaintiffs and defendants is proceeding in the MDL, however, all defendant-specific discovery has been stayed.

On December 21, 2012, NECC, the manufacturer of the contaminated MPA, filed a petition for bankruptcy protection under Chapter 11 of the bankruptcy code. See In re: New England Compounding Pharmacy, Inc., debtor, United States Bankruptcy Court for the District of Massachusetts, Case No. 12:19882 HJB. In recent months, NECC as well as numerous third party defendants, including NECC's insurers, the company hired to maintain the sterility of NECC's compounding facilities, and several defendant clinics, have agreed to a multi-million dollar settlement to be distributed to tort claimants who filed claims with the U.S. Bankruptcy Court. The settlement has been approved by the Bankruptcy Court.

Following the meningitis outbreak, the U.S. Government investigated the facilities, operations, employees, and ownership of NECC resulting in multiple indictments of NECC higher-ups. See Criminal Indictments and Preliminary Allegations, United States v. Cadden et al., 14-CR-10363, attached hereto as Exhibit A. As part of the criminal investigation, numerous individuals with unique knowledge of NECC testified in front of the federal Grand Jury for the District of Massachusetts. The government has made efforts to keep secret much of what was produced through their investigation. To date, the transcripts from the grand jury proceedings have not been shared with the parties involved in the civil proceedings in the MDL, along with millions of pages of documents and photographs accumulated and exchanged during the course of the criminal investigation. Several witnesses were granted immunity prior to appearing before the grand jury. The government has also sought orders staying certain depositions while

allowing others to proceed. The criminal case was recently set for trial on April 4, 2016.

In the instant motion, the defendants request access to limited portions of the grand jury transcripts which would be reasonably calculated to lead to the discovery of admissible evidence. If the court does not find that production of the transcripts is prudent at this time, the defendants would alternatively ask the court reconsider their request on a later date following the conclusion of the criminal trial. If a delay in disclosure would be appropriate, the defendants request that, in the interim, a full list of the individuals who testified during the grand jury proceedings be made available to the civil defendants in the MDL.

LEGAL ARGUMENT

The defendants plead pursuant to several federal rules of civil and criminal procedure. Federal Rule of Civil Procedure 26(b)(1) provides:

Unless otherwise limited by court order, the scope of discovery is as follows: Parties may obtain discovery regarding any non-privileged matter that is relevant to any party's claim or defense – including the existence, description, nature, custody, condition, and location of any documents or other tangible things and the identity and location of persons who know of any discoverable matter. For good cause, the court may order discovery of any matter relevant to the subject matter involved in the action. Relevant information need not be admissible at the trial if the discovery appears reasonably calculated to lead to the discovery of admissible evidence. All discovery is subject to the limitations imposed by Rule 26(b)(2)(C).

The United States Supreme Court has held that Rule 26 must be "construed broadly to encompass any matter that bears on, or that reasonably could lead to other matters that could bear on, any issue that is or may be in the case." Oppenheimer Fund, Inc. v. Sanders, 437 U.S. 340, 351 (1978).

Federal Rule of Criminal Procedure 6(e)(3)(E)(i) provides that "the court may authorize disclosure—at a time, in a manner, and subject to any other conditions that it directs—of a grand jury matter: (i) preliminarily to or in connection with a judicial proceeding." In <u>United States</u> v. <u>Socony Vacuum Oil Co.</u>, the Supreme Court noted that, once the grand jury's functions are

ended, "disclosure is wholly proper where the ends of justice require it." 310 U.S. 150, 234 (1940).

The Supreme Court observed in <u>Douglas Oil Co. of California</u> v. <u>Petrol Stops Northwest</u> that federal grand jury materials may be released if a party shows "that the material which they seek is needed to avoid a possible injustice in another judicial proceeding..." and that "the need for disclosure is greater than the need for continued secrecy." 441 U.S. 211, 223 (1979); <u>see also Federal Deposit Insurance Corporation</u> v. <u>Ernst & Whinney</u>, 921 F.2d 83 (1990). Any request for grand jury materials must be "structured to cover only material" as to which a particularized need for disclosure has been shown. <u>Liberty Mutual Insurance Company</u> v. <u>Diamante</u>, 193 F.R.D. 15 (2000) (quoting <u>Douglas Oil</u>, 441 U.S. at 222). <u>Douglas Oil</u> also instructs that the court must consider the public interest in grand jury secrecy on the facts of the particular case appertaining at the time the request is made. 441 U.S. at 222. The court's duty is to weigh carefully the competing interests in light of the relevant circumstances. <u>Id.</u> at 223.

A. <u>Disclosure of the Grand Jury Transcripts Is Necessary to Avoid Injustice in the State</u> <u>Proceedings</u>

The defendants submit that a limited and discreet review of grand jury transcripts in this matter is of critical importance to the defendants in the MDL. The grand jury deliberations in the criminal matter at issue revealed, as can be determined by the resulting indictment, evidence to support the charging and subsequent arrests of the NECC higher-ups. See Exhibit A. The indictment papers explain in great detail the failures of NECC to comply with federal regulations regarding pharmaceutical compounding, and go into horrifying detail regarding the unsanitary conditions of the compounding facility. See id. The Preliminary Allegations filed by the U.S.

Government describe the harmful practices exhibited by NECC (the compounding pharmacy), Medical Sales Management (the corporation who partially owned and provided sales and administrative services to NECC), and other associated parties. <u>Id.</u> at 2. The entities' ownership, management, pharmacists, and sales directors were indicted criminally for engaging in multiple nefarious activities, including but not limited to (1) using expired ingredients and generating fictitious expiration dates, (2) failing to properly sterilize and test compounded medications, (3) improper labeling, (4) improper cleaning and disinfecting, (5) inadequate personnel training, (6) defrauding customers and regulators about USP-797 compliance, environmental monitoring, and end-product testing, and even (7) employing a pharmacy technician who had surrendered his pharmacy license. <u>Id.</u> at 2-15, 18-25, 44-46.

Testimony regarding the actions of those who are being prosecuted for causing the contamination that injured the plaintiffs in each of the civil actions would be invaluable to the comparative fault defense being offered by many of the MDL defendants, and it would be reasonably calculated to lead to the discovery of admissible evidence. The testimony upon which the indictments are based would necessarily lend support to many of the pain clinic defendants in the MDL who relied upon NECC to provide sterile medications for their patients. The Saint Thomas Entities summarized this argument in their recent Memorandum in Support of Saint Thomas Entities' Motion to Compel Invoking Defendants to Produce Certain Documents: "Many of the civil defendants intend to establish its defense that the persons who caused or contributed to the contamination are solely responsible for the plaintiffs' damages, and whether couched as 'proximate cause,' 'unforseeability,' or 'no breach,' this evidence is highly relevant regardless of what law is applied or where the case is tried." See Docket. No. 2118 at p. 6.

As held in Douglas Oil, the defendants are required to present a "possible injustice" that

could occur in the event that grand jury materials are withheld throughout the duration of the civil case. 441 U.S. at 223. Nondisclosure of the transcripts would result in the MDL defendants proceeding to trial without being provided an opportunity to examine the unique knowledge possessed by the individuals who worked at NECC or who oversaw its day-to-day operations. The value of the planned "Bellwether" trials would be vastly diminished if comparative fault discovery continues to be limited by nondisclosure. The knowledge shared by NECC employees and management is unique because the defendants have no other way to obtain this first-hand information from secondary sources. While there were inspections performed at the facility, one conducted by the plaintiffs' expert Dr. Philip J. Austin during the immediate aftermath of the outbreak and another conducted in July 2014 by Robert Kaiser, president of Liberty Industries, Inc., neither individual was a percipient witness to the daily operations of the Framingham facility prior to the outbreak. Similarly, while 30(b)(6) witnesses have been deposed from the various companies who constructed, maintained, and cleaned NECC's clean rooms and ventilation systems, these individuals were not under the employ of NECC and therefore were not present at the facility while medications were being compounded.

The key witnesses to NECC's fault in solely causing the meningitis outbreak are refusing to testify, and the court has granted certain witnesses protection from a deposition. See Docket No. 2123. While several notable witnesses have been compelled to testify, the defendants anticipate a blanket invocation of the 5th Amendment with regard to any testimony pertaining to their relationship to NECC. For example, Steve Higgins, a witness with a direct connection to the management of the Framingham facility, was deposed on September 9, 2015. See Deposition of Steve Higgins, attached hereto as Exhibit B. His deposition illustrates the significant hurdle facing the MDL defendants as they attempt to obtain direct evidence of

NECC's day-to-day operations. <u>See id.</u> For the duration of a deposition lasting approximately three hours, Mr. Higgins answered almost every question by stating, "On the advice of counsel, I respectfully exercise my 5th and 14th Amendment rights and decline to answer that question." <u>See id.</u> The defendants expect that future witnesses closely connected to NECC, certainly those witnesses investigated or charged in connection with the underlying criminal matter, to respond in the same manner at his/her own deposition.

Without being privy to the testimony presented to the grand jury, the parties must speculate as to what the witnesses said and what exhibits were introduced. However, given the information provided by the indictment papers, the defendants contend that it is reasonable to assume that the transcripts would contain highly specific information about the following outstanding questions: (1) what procedures were followed by NECC employees to compound medications, (2) in which rooms were certain medication lots compounded, (3) in what manner were compounding procedures provided to employees, (4) how did compounding methods differ for each of the medications compounded at the facility, (5) were the employees aware of any defects in their compounding procedures, (6) were the employees aware of any defects in clean room construction or maintenance, (7) did the employees object to any instructions or orders handed down by management, (8) how were the compounded medications tested and how often, (9) how were the clean rooms inspected and how often, and (10) what strategies and materials were used to market NECC's products. See Exhibit A. The defendants have gained insight into several of these issues by deposing third party witnesses, examining physical evidence, and reviewing documents produced through common discovery, however, the most relevant information can only be provided by the witnesses directly involved in NECC's operations. Revealing the most relevant portions of the grand jury transcripts would alleviate this "possible

injustice" shared by the majority of the defendants in the MDL who should be warranted to thoroughly assess the full scope of NECC's behavior during the relevant time period at issue in these cases.

It is the belief of the defendants that relevant grand jury testimony in the criminal matter at issue will reveal exculpatory information regarding the misrepresentations made by NECC employees to defendant pain clinics, including Ocean State Pain Management, who believed, based on information that they were given, that NECC was compliant with federal and state compounding regulations. It is the contention of the defendants that NECC made numerous misrepresentations to the defendant clinics, including claims that NECC was USP 797-compliant and maintained their clean rooms pursuant to federal and state regulations. The indictment papers released regarding the arrests of the fourteen NECC higher-ups allege that there was intentional misrepresentation in these areas. See Exhibit A at 2-15, 18-25, 44-46. Without the limited release of relevant portions of the grand jury transcripts, the defendants in the instant case would be unjustly hindered in their defense. The limited portions of the transcripts relevant to (1) NECC's compliance or noncompliance with federal and state regulations regarding compounding pharmacies, (2) the sanitary conditions at NECC's Framingham facility, and (3) information provided by NECC to customer clinics regarding such compliance would enable the health care provider defendants to establish for civil juries why NECC should be allocated 100% of the fault for the contamination.

B. The Need for Disclosure Is Greater than the Need for Continued Secrecy

The Supreme Court requires that "the need for disclosure [be] greater than the need for continued secrecy." <u>Douglas Oil Co.</u>, 441 U.S. at 223 (1979). The purposes for grand jury

secrecy were set out in United States v. Amazon Industrial Chemical Corp.: (1) to prevent the escape of suspects before indictment can be accomplished, (2) to protect the freedom of grand jury deliberations, (3) to prevent tampering with grand jury witnesses before their testimony is given at a public trial, (4) to encourage unrestrained disclosures by grand jury witnesses, with no fear of retaliation, and (5) to protect a suspect found innocent by the grand jury. 55 F.2d 254, 261 (D. Md. 1931). The first, second, and fifth bases have limited applicability once an indictment has been returned and the grand jury is dismissed, especially in the context of a subsequent civil case. See id.; United States v. Proctor & Gamble Co., 356 U.S. 677, 682 (1958). The third basis would remain relevant as a balancing factor until the criminal trial has ended. See id. The fourth basis would only remain applicable in order to, according to the Supreme Court, encourage future grand jury witnesses to testify freely. See id. In Fleet National Bank v. Export-Import Bank of the United States, the court made the significant point that the general purpose of Rule 6(e) is to "protect from disclosure only the essence of what takes place in the grand jury room, in order to preserve the freedom and integrity of the deliberative process." 612 F.Supp. 859, 867 (1985) (quoting In re Grand Jury Investigation (New Jersey State Commission of Investigation), 630 F.2d 996, 1000 (3rd Cir. 1980)) [emphasis added].

For several reasons, the policy considerations expected to be advanced by the government are insufficient to warrant a denial of the defendants' request. See U.S Government's Motion to Intervene and for a Stay of Certain Depositions Pending Resolution of Related Criminal Proceedings and Opposition to the Saint Thomas Entities' Motion to Compel Production of Criminal Discovery, Docket No. 2209. The government is expected to argue that the defendants' request would create substantial pretrial publicity about the testimony of several witnesses the government intends to call at the criminal trial. See id. at 14. The government is

expected to argue that disclosure would result in leaks and disclosures prior to trial, which would affect the government's ability to seat a fair and impartial jury and harm the rights of the fourteen criminal defendants to a fair trial. See id. Finally, the government is expected to contend that disclosure would prematurely and broadly disclose statements of government witnesses and essential elements of the government's case in chief, allowing the criminal defendants to tailor defenses to fit the anticipated proof. See id.

The detailed indictments that resulted from the grand jury deliberations are not sealed, but rather, are a matter of public record. Further, the grand jury has completed its deliberations on this matter, and there does not appear to be a plan in place to compel future witnesses to testify in advance of the April 4, 2016 trial date. The defendants additionally submit that the events and actions from which the criminal charges have arisen have been widely publicized and covered by media outlets, from the time of the outbreak in 2012 to the time of the arrests and arraignments in 2014. These matters have been in the public eye since the very first case of meningitis, and can hardly be said to be under a cloak of secrecy. Thus far, there have been no complaints that discovery has been shared or leaked in violation of any protective orders in the MDL. Current protective orders only cover personal health and financial information, and the civil defendants' request does not seek such information. Finally, in its Motion to Intervene, the government feared that the criminal defendants could participate in certain depositions due to the lack of an order preventing such an action, however, the instant motion presents a different scenario. See id. The court could issue a protective order prohibiting the criminal defendants from accessing grand jury minutes that have not previously been disclosed to them by the government in the criminal case. More importantly, the criminal defendants have since been dismissed from the civil case which provides further assurance that they will not have access to

the grand jury minutes. <u>See</u> Order Dismissing Claims Against Settling Defendants, Docket No. 2193.

The court in Ernst & Whinney noted that the grand jury investigation was still ongoing in the underlying criminal matter and that the need for secrecy was therefore difficult to overcome by a litigant seeking grand jury materials. See 921 F.2d at 87. Unlike in Ernst & Whinney, the grand jury investigation in the NECC criminal matter has long since concluded, indictments have been returned, and a trial date has been set. While the grand jury secrecy rule is upheld in the majority of scenarios, and the identity of witnesses or jurors, the substance of testimony, the strategy or direction of the investigation, the deliberations or questions of jurors, are typically protected, see SEC v. Dresser Industries, Inc., 628 F.2d 1368, 1382 (D.C.Cir. 1980), the principle does not "foreclose from all future revelation to proper authorities the same information or documents which were presented to the grand jury." New Jersey State Commission, 630 F.2d at 1000. The same court quoted at length from United States v. Interstate Dress Carriers, Inc., 280 F.2d 52, 54 (2d Cir. 1960): "When testimony or data is sought for its own sake - for its intrinsic value in the furtherance of a lawful investigation – rather than to learn what took place before the grand jury, it is not a valid defense to disclosure that the same information was revealed to a grand jury or that the same documents had been, or were presently being, examined by a grand jury."

Just as in <u>Interstate Dress Carriers</u>, the defendants here are seeking testimony or data "for its own sake - for its intrinsic value in the furtherance of a lawful investigation." <u>See id.</u> The strategy or direction of the criminal investigation conducted by the government is not sought by the interested parties, though such information is necessarily and intrinsically tied to the anticipated substance of the grand jury testimony. The defendants in the civil suit seek

information that has proven to be unattainable by other means. The defendants contend that the holding of the court in <u>Socony-Vacuum Oil Co.</u> applies here, that in some instances, once the functions of the grand jury have terminated, disclosure might ensure where application of the traditional rule would be inconsistent with the "ends of justice." <u>See</u> 310 U.S. 150, 234 (1940).

In Liberty Mut. Ins. Co., individuals were charged in a criminal case in the District of Massachusetts (Cr. No. 99-10130-JLT) in connection with activities which also formed the basis for a civil complaint. 193 F.R.D. at 17. The criminal charges against the defendants were in the form of an indictment by a grand jury. Id. The plaintiffs in the civil action served a request for production of documents upon the two defendants which sought "[a]ll transcripts and exhibits in the possession of [the defendants] or [their] attorneys from grand jury proceedings in the criminal investigation in Criminal Action No. 99-10130 against [the defendants]." Id. The defendants objected on the ground that Rule 6(e), Fed. R. Crim. P., prohibited them from disclosing the materials requested and that the request was "burdensome, harassing and improper." Id. The defendants' argument with regard to the grand jury secrecy rule failed. Id. at 18. The court overruled the defendants' objections stating that Rule 6(e), Fed. R. Crim. P., imposed no rule of secrecy upon the defendants. Id. The general rule of secrecy imposed by criminal procedure rules did not preclude defendants in a criminal case from disclosing grand jury materials to plaintiffs in a related civil case. Id. The only objection sustained by the court was that the plaintiffs had failed to provide notice to the U.S. Attorney that they were seeking disclosure of grand jury materials. Id.

The government has made similar objections to the production of grand jury testimony based on the general secrecy rule. See United States v. Bulger, 283 F.R.D. 46, 48 (D. Mass. 2012). The defendant and a newspaper sought to lift the government's protective order covering

materials it had produced. Id. The government argued that the production included "highly sensitive documents," including grand jury transcripts that should remain protected. Id. The court held that it was "difficult to fathom" that all of the documents produced were "sensitive, confidential, grand jury testimony, Title III material or otherwise suitable and appropriate for continued protection," and rejected the government's blanket assertions. Id. at 54, 55, and 58. It required the government to identify by category and Bactes number each document that it contended should remain subject to continued protection, including documents related to grand jury proceedings. Id. The government's argument should also be rejected here for the same reasons. The sought-after portions of grand jury transcripts could be ordered pursuant to the protective orders described previously, and the court has the option of performing an in camera review of the grand jury transcripts to ascertain which portions can be appropriately disclosed to the defendants. The court in Ernst & Whinney suggested that an index of grand jury materials could be produced following the private party's showing of particularized need. 921 F.2d at 87. That index would be provided to the district court judge or magistrate and would not be made public or available to the moving party. Id.

C. <u>The Defendants' Request for Grand Jury Transcripts Is Not Overbroad or Unduly</u> <u>Burdensome</u>

The Saint Thomas Entities' recently argued its Motion to Compel Invoking Defendants to Produce Certain Documents in an attempt to gain access to 8.7 million documents provided by the government to the criminal defendants. See Docket No. 2118. The argument made by the Saint Thomas Entities mimics the instant motion since an increasing number of defendants are cognizant of the fact that ample evidence regarding NECC's operations and representations to

potential customers remains absent from common discovery. See id. The Saint Thomas Entities argued that (1) the evidence they sought was highly relevant to the NECC MDL, (2) the Invoking Defendants were the sole persons in the MDL with possession, custody, and control of most, if not all, of the relevant evidence at issue, (3) the Saint Thomas Entities were not seeking extraordinary relief and the burden of production on the Invoking Defendants was minimal, and (4) the civil cases cannot possibly go forward before the criminal trial unless the health care defendants are provided equal access to the evidence on NECC's culpability. Id.

Judge Boal denied the motion reasoning that the Saint Thomas Entities failed to show sufficient relevance for all of the requested documents. See Order on Saint Thomas Entities' Motion to Compel Invoking Defendants to Produce Certain Documents and Invoking Defendants' Cross-Motion for Protective Order, Docket No. 2240. The blanket request for all 8.7 million pages was overly broad and failed to demonstrate any particularized need for the materials. Id. The request was also found to be unduly burdensome and time-consuming. Id. Finally, Judge Boal ruled that any grand jury materials previously received by the Invoking Defendants are not discoverable unless the Saint Thomas Entities show that the "material which they seek is needed to avoid a possible injustice in another judicial proceeding" and that "the need for disclosure is greater than the need for continued secrecy."

The defendants have attempted to address each of Judge Boal's concerns in the instant motion and memorandum. While the defendants share many of the arguments offered by the Saint Thomas Entities, the instant request is far less broad and burdensome. The defendants' request is tailored to limited portions of grand jury minutes, and the court would necessarily have discretion over which portions of the transcripts should be produced.

In Liberty Mutual, the court did not reach the question of whether the plaintiffs' request

was overbroad but it did suggest that the teachings of the <u>Douglas Oil</u> case were applicable. 193 F.R.D. at 18-19. (citing <u>Douglas Oil</u>, 441 U.S. at 222). To the extent that the plaintiffs' request was a broad request for "all transcripts and exhibits," the court instructed the plaintiffs to file a motion to compel production of grand jury materials seeking disclosure of only those specific materials as to which the plaintiffs were able to demonstrate a particularized need. <u>Id.</u> The defendants have attempted to address the court's concerns by only requesting the most relevant portions of the grand jury transcripts.

D. The Defendants' Request is Limited to Testimony on Certain Topics and Thus Structured to Cover Only Material So Needed

The Supreme Court requires that a request for release of Grand Jury materials, including transcripts of testimony, be "structured to cover only material so needed." <u>Douglas Oil</u>, 441 U.S. at 211. The defendants are aware, from the numerous charges articulated in the indictment in the criminal matter, that testimony spanned topics from compliance with compounding regulations to conspiracy to commit structuring. <u>See</u> Exhibit A. In <u>Proctor & Gamble Co.</u>, the Supreme Court established that disclosure would be granted to individual litigants only upon a showing of "particularized need." 356 U.S. at 677. "Particularized need" has not been defined by the Court, however, it is clear that an articulated, non-frivolous need for grand jury materials is, at the least, expected. <u>See id.</u> General helpfulness in preparing one's case for trial is not sufficient to constitute "particularized need." <u>City of Philadelphia v. Westinghouse Electric Corp.</u>, 210 F. Supp. 486, 489 (E.D. Pa. 1962).

In <u>U.S. Industries</u> v. <u>United States District Court</u>, the court permitted disclosure of grand jury materials when "discovery leads" was provided as the particularized need, reasoning that

"[i]f the reasons for maintaining secrecy do not apply at all in a given situation, or apply only to an insignificant degree, the party seeking disclosure should not be required to demonstrate a *large* compelling need. 345 F.2d 18, 21 (9th Cir. 1965) [emphasis added]. As set out in Section B, the secrecy concerns listed in <u>Amazon Industrial Chemical Corp.</u> apply only to an insignificant degree now that the criminal matter is approaching a trial date, and therefore the civil defendants should not be required to demonstrate a "large" compelling need. <u>See</u> 55 F.2d at 261; <u>U.S. Industries</u>, 345 F.2d at 21.

The first federal decision allowing civil plaintiffs limited disclosure of a civil defendant's grand jury minutes for deposition purposes employed two justifications for the invasion of the secrecy rule. Westinghouse Electric Corp., 210 F. Supp. at 486; see also Note, Release of Grand Jury Minutes, in the National Deposition Program of the Electrical Equipment Cases, 112 U. Pa. L. Rev. 1133, 1141 (1964). The justifications were the unique nature of the nation-wide deposition program involved, and the fact that some plaintiffs were agencies charged with protecting the public's interest. See id. While early case law disfavored disclosure for purely discovery purposes, that sentiment began to shift and disclosure for discovery purposes was subsequently permitted where the reasons behind the rule of grand jury secrecy were no longer applicable to any significant degree and/or where the party seeking disclosure would be at a disadvantage if grand jury material was not provided to him. A group of cases granting disclosure also considered the fact that the party opposing the request had knowledge of the grand jury proceedings while the requesting party did not. See U.S. Industries, 345 F.2d at 18; In re Cement-Concrete Block, 381 F. Supp. 1108 (N.D. Ill. 1974); Connecticut v. General Motors Corp., 323 U.S. 373 (1945). In the instant civil case, plaintiffs and defendants across the country have had their cases transferred to the MDL, and multiple depositions have been conducted on a

weekly basis throughout the calendar year. NECC's operations have directly affected public health on a massive scale. The defendants' request for grand jury minutes invokes the court's concerns from Westinghouse and is narrowly tailored to obtain only those portions of the transcripts containing information not discoverable by other means.

In Ernst & Whinney, the private party merely subpoenaed grand jury documents from the Federal Bureau of Investigation and did not make any particularized showing. 921 F.2d at 86-87. The court noted that the documents sought could be obtained through ordinary discovery, i.e. subpoenaing the documents from other sources or pursuing other routine avenues of investigation. Id. The court also noted that the requesting party could have attempted to rebut the presumption that the sought-after documents were otherwise available by civil discovery, but they failed to do so. Id. at 87. In the instant case, the discovery at issue in the grand jury transcripts has proven to be unattainable by other means. Witnesses have been protected from deposition, witnesses closely tied to NECC have plead and are expected to continue to plead the 5th Amendment, and the Saint Thomas Entities' recent Motion to Compel Certain Documents has been denied. If forced to await the conclusion of the criminal matter next year, the MDL defendants would continue to be prejudiced by the nondisclosure of highly relevant comparative fault discovery described in Section A, or worse, certain civil cases could reach trial before the criminal trial concludes. As such, the defendants seek only those transcripts which include testimony relevant to (1) NECC's compliance with federal and state regulations regarding compounding pharmacies, (2) the sanitary conditions at NECC's Framingham facility, and (3) information provided by NECC to customer clinics regarding compliance with applicable federal and state pharmacy regulations. The defendants' request is limited to testimony addressing NECC's compliance with 247 C.M.R. § 9.01(3) and United States Pharmacopeia Ch. 797, which

regulate compounding pharmacy practices in Massachusetts and nationally, as well as any testimony specifically regarding information and representations conveyed to customer clinics and medical providers ordering methylprednisolone acetate from NECC.

CONCLUSION

The defendants plead that the limited and discreet release of portions of grand jury testimony from the criminal matter <u>United States v. Cadden et al.</u>, 14-CR-10363 would prevent injustice in aiding their defense of plaintiffs' claims. The arguments supporting disclosure in this instance outweigh the interest in secrecy of the proceedings, based on the value of the grand jury testimony to the instant case and the minimal level of secrecy that the criminal proceedings have been afforded thus far. Finally, the defendants limit their request to testimony on specific topics in compliance with the Supreme Court's instruction in <u>Douglas Oil Co.</u>

WHEREFORE, the defendants, Abdul R. Barakat, M.D., and Ocean State Pain Management, P.C., respectfully request that this Honorable Court issue a court order compelling the U.S. Government to release relevant portions of grand jury transcripts in the criminal matter, United States v. Cadden et al., 14-CR-10363.

Respectfully submitted,

By their attorneys,

/s/ Thomas M. Dolan

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CERTIFICATE OF SERVICE

I hereby certify that on October 28, 2015, I served the above Memorandum upon the Clerk of the Court, using the CM/ECF system, which then sent a notification of such filing (NEF) to all counsel of record.

/s/ Thomas M. Dolan

THOMAS M. DOLAN, ESQ.

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